

57. The method for storing medicine according to Claim 56, wherein the medicine is contained within a vial.--

REMARKS

Prior to an examination on the merits of the above-identified patent application, entry of new Claims 33-57, as presented herein, is respectfully requested.

The present application now contains Claims 1-57, of which Claims 1, 29, 33 and 56 are presented in independent form.

New Claims 33-57 recite the subject matter of Claims 1-23, as amended and examined during the Chapter II, P.C.T. international phase of Applicants' corresponding P.C.T. Application, No. PCT/GB97/02930, of which the instant U.S. patent application is a "by-pass" continuation-in-part application thereof.

More particularly, in the prosecution of P.C.T. Application No. PCT/GB97/02930, the European Patent Office, acting as the examining authority (IPEA/EP) during the Chapter II international phase of said P.C.T. application, has issued its International Preliminary Examination Report holding amended Claims 1-23 of Applicants' international application to be patentable over the prior art. New Claims 33-57 of the instant U.S. patent application recite the subject matter of the "allowed" international claims. (A copy of Applicants'

International Preliminary Examination Report, issued January 22, 1999, is enclosed.)

Applicants respectfully request that the Examiner's first Office Action, yet to be received, include consideration of the claims presented in this Preliminary Amendment, as well as those claims pending in the application, when filed.

In light of the pendency of twenty-five (25) additional claims, as well as the pendency of a forth independent claim, Applicants herein remit the additional claims fee (small entity) of \$264.00.

Accordingly, an early examination of the merits of pending Claims 1-57 and allowance thereof are, therefore, respectfully requested and earnestly solicited.

Respectfully submitted,  
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Enc.: 1. Applicants' International Preliminary Examination Report in P.C.T. Application No. PCT/GB97/02930;  
and,  
2. Check for \$264.00 (Additional Claims Fee).

The Commissioner is hereby authorized to charge the Deposit Account of Applicant's Attorney, Account No. 19-0450, for any additional fees which may be due in connection with the prosecution of the present application (except pre-payment of the Issue Fee), but which have not otherwise been provided for.

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**PATENT COOPERATION TREATY**

**PCT**

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P66565WO	<b>FOR FURTHER ACTION</b>		See Notification of Transmittal of International Preliminary Examination Report (PCT/IPEA/416)
International application No. PCT/GB97/02930	International filing date (day/month/year) 23/10/1997	Priority date (day/month/year) 23/10/1996	
International Patent Classification (IPC) or national classification and IPC A61J1/16			
Applicant WOLSEY, Henry Garnet et al			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I     Basis of the report
- II     Priority
- III     Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV     Lack of unity of invention
- V     Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI     Certain documents cited
- VII     Certain defects in the international application
- VIII     Certain observations on the international application

Date of submission of the demand 20/05/1998	Date of completion of this report 22.01.99
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**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/GB97/02930

**I. Basis of the report**

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

**Description, pages:**

1-7 as originally filed

**Claims, No.:**

1-23 as received on 09/12/1998 with letter of 08/12/1998

**Drawings, sheets:**

1/2,2/2 as originally filed

2. The amendments have resulted in the cancellation of:

the description, pages:  
 the claims, Nos.:  
 the drawings, sheets:

3.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/GB97/02930

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes:	Claims 1-23
	No:	Claims
Inventive step (IS)	Yes:	Claims 1-23
	No:	Claims
Industrial applicability (IA)	Yes:	Claims 1-23
	No:	Claims

**2. Citations and explanations**

**see separate sheet**

**VI. Certain documents cited**

**1. Certain published documents (Rule 70.10)**

and / or

**2. Non-written disclosures (Rule 70.9)**

**see separate sheet**

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

**see separate sheet**

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB97/02930

**SECTION VI**

**1. Certain published documents (Rule 70.10)**

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
US-A-5 60 6746	04/03/97	21/12/94	

**SECTION V**

**2. Document D1 = US-A-4 908 248 discloses (see the embodiment according to figure 23 and the corresponding parts of the description) a portable flexible pouch suitable for cooling and storing vials and the like, comprising**

- a) double-skinned textile web member of water permeable material, said web member including a first double skinned web-portion (12 with flaps 15 and 19) interconnected via a hinge portion to a second web portion (13,17) (see in particular column 4, line 63 to column 5, line 2);**
- b) fastening means (17b, 19b) for fastening remaining edges of the first web portion to the second web portion;**

wherein the first web member includes a plurality of compartments each containing water absorbent granular material which is capable of alternately absorbing water and desorbing water on drying out, said polymeric material having a transition between respective hydrated forms at or close to ambient temperature, the hinge portion being free of compartments containing said material.

**3. The pouch according to claim 1 differs from this prior art in that the second web portion is also double skinned (and also includes a plurality of compartments each containing water absorbent granular material), and in that the hinge portion is defined by a row of stiches and said compartments are separated from one another by stiches, said stiches connecting the respective skins of said double-skinned textile member.**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/GB97/02930

4. The problem to be solved by the invention can thus be seen in improving the cooling capacity of the pouch and minimising the conductive paths through the walls.
5. The solution proposed in claim 1 is considered as involving an inventive step (Article 33(3) PCT) since no available documents suggests the new features and since it is not obvious to modify the pouch according to D1 in the claimed manner.
6. For the same reasons the subject-matter of claim 22 for a method also involves an inventive step.
7. Claims 2-21 and 23 are dependent claims and as such also meet the requirements of the PCT with respect to novelty and inventive step.

**SECTION VII**

8. The independent claim 1 has not been properly cast in the two part form, with those features which in combination are part of the nearest prior art (see document D1) being placed in the first part. It, therefore, does not meet the requirements of Rule 6.3 (b) PCT.
9. Reference signs in parentheses should have been inserted in the claims to increase their intelligibility, Rule 6.2(b) PCT. This apply to both the preamble and characterising portion.

**SECTION VIII**

10. Claim 1 is not clear since in paragraph a) it refers to "compartments" and to "said polymeric material" which are only defined later in the claim.

## CLAIMS:

1. A portable flexible pouch for cooling and storing vials and the like, said pouch comprising:
  - (a) a double-skinned textile web member of water permeable material, said web member including a first double-skinned web portion interconnected, directly or indirectly, via a hinge portion at an edge thereof to a second double-skinned web portion, said hinge portion being free of compartments containing said polymeric material; and
  - (b) fastening means for fastening remaining edges of said first web portion to said second web portion, wherein at least one of said web portions includes a plurality of compartments each containing water absorbent granular polymeric material which is capable of alternately absorbing water and desorbing water on drying out, said polymeric material having a transition between respective hydrated forms at or close to ambient temperature, characterised in that said hinge portion is defined by a row of stitches and said compartments are separated from one another by stitches, said stitches connecting the respective skins of said double-skinned textile member.
2. A pouch according to claim 1, wherein each of said web portions comprises a plurality of said compartments.
3. A pouch according to claim 1 or 2, wherein each of said web portions is of a quadrilateral shape.
4. A pouch according to any of claims 1 to 3, wherein said fastening means comprise at least one first element comprising a multiplicity of hooks, and at least one complementary second element comprising a multiplicity of loops engageable with said hooks.

5. A pouch according to claim 4, wherein said complementary elements are in the form of strip or tape.
6. A pouch according to any of claims 1 to 5, wherein said web members are arranged to be fastened together by said fastening means in such a way that one end of the one said web member extends beyond a free edge of the other of said web members, so as to form a flap foldable over a marginal portion of said other web portion.
7. A pouch according to claim 6, wherein said flap has fastening means on a first face of said web portion for engagement with complementary fastening means on the marginal portion on said other web portion.
8. A pouch according to any of claims 1 to 7, wherein said edges are along longitudinally extending edges of the respective web portions.
9. A pouch according to any of claims 1 to 8, wherein said textile material comprises a woven fabric.
10. A pouch according to claim 9, wherein said woven fabric comprises a polyester/cotton fabric blend.
11. A pouch according to any of claims 1 to 10, wherein said polymeric material comprises an acrylic polymer.
12. A pouch according to claim 11, wherein said acrylic polymer comprises a cross-linked acrylate or methacrylate polymer.

13. A pouch according to any of claims 1 to 12, wherein said compartments containing said water absorbent material are formed by sewing an elongate double skinned web member in sewing lines extending along the length of said web portion.
14. A pouch according to claim 13, which includes a plurality of said sewing lines so as to divide said web portions lengthwise into a plurality of said compartments.
15. A pouch according to claim 14, wherein at least one further sewing line is provided transverse to said lengthwise direction.
16. A pouch according to any of claims 1 to 15, wherein said hinge portion connects on edge of said first web portion directly to second web portion.
17. A pouch according to any of claims 1 to 15, wherein said hinge portion connects on edge of said first web portion indirectly to said second web portion.
18. A pouch according to claim 17, wherein an intervening panel connects said hinge portion to said second web portion.
19. A pouch according to claim 17 or 18, wherein the pouch forms a substantially closed box.
20. A pouch according to claim 19, wherein said second web portion provides a closure for a tray constituted by said first web portion, said intervening panel and a plurality of edge panels.

21. A pouch according to claim 20, wherein said first web portion, said second web portion, said intervening panel and said edge panels are formed from a single web.
22. A method of storing medicine with comprises treating said web portions of a pouch according to any of claims 1 to 21 with cold water, so as to cause swelling of said water absorbent material within said compartments, and disposing said medicine within the pouch while the compartments contain the swollen water absorbent material.
23. A method according to claim 22, wherein said medicine is contained within a vial.